CardioLab®II Plus Amplifier

Operator's Manual

2002938-001 Revision B

GE Medical Systems
Information Technologies

gemedicalsystems.com

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Warranties
Cardiology Products

Scope of Warranties

Product Warranty: We warrant to you that all new cardiology Products made by us and sold by us or our authorized representatives (the "Warranted Products") will (1) be free from defects in title and in material and workmanship under normal use and service; and (2) except for Warranted Products manufactured in compliance with your designs or specifications, substantially comply with our technical written specifications on the date such Warranted Products are shipped to you (the "Product Specifications"). The Product Specifications are available upon request.

Year 2000 Compliance Warranty: We warrant to you that the Warranted Products are "Year 2000 Compliant" or will be made by us "Year 2000 Compliant" at no additional cost to you prior to the time when dates in 1999 or later could affect their operation. "Year 2000 Compliant" means that: (1) each Warranted Product will correctly accept, store, retrieve, compare, calculate, export, display, print out, sequence and otherwise process dates on, before and after January 1, 2000, including leap years, in accordance with the applicable Product Specifications; and (2) each Warranted Product's performance and functionality will not be materially adversely affected as a result of the date change from 1999 to 2000.

Patent and Copyright Warranty: We warrant to you that when the Warranted Products are delivered to you, they will not be subject to any valid U.S. patent or copyright infringement claim.

Warranty Limitations and Requirements

The Product Warranty is limited in time, as follows:

Prucka CardioLab® System: One year.
Prucka Mac-Lab® System: One year.
Prucka ComboLab System: One year.
Ambulatory (Holter Recorders): One year.
SEER® XT and SEER® MC: Two years.
MARS™ Analog Remote System: One year.
MARS™ Digital Remote System: One and one-half years.
Defibrillators: One year.
Resting ECG analysis and exercise testing systems (except batteries): One year.
Resting ECG analysis and exercise testing system batteries: Ninety days.
MAC 500 and MAC 1000: Three years.
Cath Lab products: One year.

The Year 2000 Compliance warranty extends through the term of the underlying Product Warranty.

The warranty period begins on the date the Warranted Products are delivered to you. If we assemble or install the Warranted Products, however, the warranty period begins on the earlier of (1) five days after the date we notify you that we have completed assembly or installation and the Warranted Products are operating in accordance the applicable Product Specifications, or (2) the date you first use Warranted Products for patient use. If assembly or installation is delayed for thirty days or more after the date of delivery for a reason beyond our reasonable control, the warranty period will begin on the thirtieth day after date of delivery, but under no circumstances will the warranty term begin later than six months following the delivery date, regardless of cause.

The warranty period for any Warranted Product or part furnished to you to correct a warranty failure will be the unexpired term of the warranty applicable to the repaired or replaced Product.

Warranty Exclusions

These warranties do not cover:

A. Any defect or deficiency (including failure to conform to Product Specifications) that in our reasonable determination results, in whole or in part, from (1) any alteration, improper storage, handling, use or maintenance, or any extraordinary use of the Products, by anyone other than us; (2) failure to maintain the Products in the manner described in any applicable instructions or specifications (including upper and lower date limits); (3) damage resulting from the use of electrodes, paper, batteries, magnetic media, patient sample line, filters, cuvettes, or other supplies not recommended by us; (4) using or combining the Products with any item or data except as specified in the applicable Product Specifications or using or combining the Products with any item or data that does not properly and unambiguously exchange data with the Products in accordance with the applicable Product Specifications; (5) any of your designs, specifications or instructions; (6) any failure of any product to use or process correct dates, except as specified in the Year 2000 Compliance Warranty; and (7) any cause external to the Products as furnished by us or beyond our reasonable control. Our warranty only applies to Products purchased or supplied from us. Service repairs resulting from failures of equipment not purchased from us are billable at standard rates.

B. The payment or reimbursment of any facility costs arising from repair or replacement of the Warranted Products or parts.

C. Any adjustment, such as alignment, calibration, or other normal preventative maintenance required of you.

D. Expendable supply items, including without limitation electrodes, magnetic media, leadwires, patient cables, all external cabling on the Prucka CardioLab and Prucka Mac-Lab, ink, and ribbons.

THE FOREGOING WARRANTIES ARE EXCLUSIVE AND IN LIEU OF ALL OTHER REPRESENTATIONS, WARRANTIES, AND COVENANTS, EXPRESS OR IMPLIED, WITH RESPECT TO THE PRODUCTS AND ANY DEFECTS THEREIN OF ANY NATURE WHATSOEVER. WE MAKE NO WARRANTIES RELATING TO MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR USE. UNDER NO CIRCUMSTANCES SHALL WE BE LIABLE TO YOU UNDER ANY TORT, NEGLIGENCE, STRICT LIABILITY, OR PRODUCT LIABILITY CLAIM AND YOU AGREE TO WAIVE ANY SUCH CLAIMS.

Exclusive Warranty Remedies

Product Warranty and Year 2000 Compliance Warranty: Our sole responsibility for any breach of any warranty is, at our option, to repair or replace the Warranted Products or parts not conforming to the warranty, in accordance with any limitations listed above, provided that you promptly notify us of your warranty claim and make such Warranted Products available for service. Warranty service will be performed without charge from 8:00am to 5:00pm, Monday through Friday, excluding our holidays, and outside those hours and days at our prevailing service rates and subject to the availability of personnel.

Warranty service for defibrillators and the MAC® PC resting ECG analysis systems will be provided on-site if the installation is located within 100 miles of any of our existing authorized service personnel, otherwise such Warranted Products must be returned to our factory. For return-to-factory warranty service, at your request, we will provide to you at no additional cost (except that you must pay all shipping charges) substantially similar temporary replacement Product until such warranty service is completed. Such temporary replacement Product will be loaned to you subject to these terms and conditions.

Patent and Copyright Warranty: We shall indemnify you for all direct and actual damages recovered from you by a third person in any legal proceedings for infringement that would be a breach of the Patent and Copyright warranty, provided that you promptly notify us in writing of the claimed infringement, permit us to assume full control of the defense thereof and cooperate with us with respect to such defense. If the infringement claim is determined by a court of competent jurisdiction to be valid, we will, at our option, also obtain a license for you to continue using the infringing Warranted Product, provide a non-infringing replacement, alter the Warranted Product so that it is non-infringing, or remove the infringing Warranted Product and refund the price (less reasonable depreciation) and any return transportation costs paid by you. If we elect not to assume the defense, we shall also indemnify you for all expenses incurred in the defense of such infringement action. In like manner, you agree to indemnify and hold us harmless from claims of patent infringements relating to our compliance with your designs or specifications

The above describes your exclusive remedies and our sole liability for any warranty claims. You agree that we and our representatives have no liability to you for (1) any penal, incidental or consequential damages, including without limitation, loss of business, goodwill, profit or revenue, (2) any assistance not required under the Quotation, or (3) anything occurring after the warranty period ends. This exclusive remedy shall not have failed of its essential purpose (as that term is used in the Uniform Commercial Code) provided that we remain willing to repair or replace defective Warranted Products within a commercially reasonable time after receiving such Warranted Products. You specifically agree that our price for our Warranted Products is based upon the limitation of our liability as set forth in these terms and conditions.

CE Marking Information

CE 0459

Compliance

The CardioLab II Plus Amplifier bears CE mark CE-0459 indicating its conformity with the provisions of the Council Directive 93/42/EEC concerning medical devices and fulfills the essential requirements of Annex I of this directive.

For devices manufactured in the United States, the CE mark is applied under the authority of Notified Body GMED (0459).

The country of manufacture and appropriate Notified Body can be found on the equipment labeling.

The safety and effectiveness of this device has been verified against previously distributed devices. Although all standards applicable to presently marketed devices may not be appropriate for prior devices (i.e. electromagnetic compatibility standards), this device will not impair the safe and effective use of those previously distributed devices.

The CardioLab II meets the requirements of EN60601-1-2 (1993-04) Medical Electrical Equipment, Part 1: General Requirements for Safety, 2. Collateral Standard: Electromagnetic compatibility - Requirements and tests.

Exception

ECG Parameter

IEC601-1-2 clause 36.202.1 - Immunity: Radiated Immunity –

The level of compliance is less than 1V/m

If operating under the conditions defined in EMC Standard EN60601-1-2 (Radiated Immunity 3V/m), field strengths less than 1V/m may cause waveform distortions and erroneous numeric data at various electromagnetic interference (EMI) frequencies.

Recommendations: –

Review the AAMI EMC Committee technical information report (TIR-18) titled Guidance on electromagnetic compatibility of medical devices for clinical / biomedical engineers - Part 1: Radiated radio-frequency electromagnetic energy. This TIR provides a means to evaluate and manage the EMI environment in the hospital.

The following actions can be taken:

- managing (increasing) distance between sources of EMI and susceptible devices
- managing (removing) devices that are highly susceptible to EMI
- lower power from internal EMI sources under hospital control (i.e. paging systems)
- labeling devices susceptible to EMI
- educating staff (nurses and doctors) to be aware of, and to recognize, potential EMI related problems

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For your notes

Manual Information

Revision History

Each page of the document has the document part number and revision letter at the bottom of the page. The revision letter identifies the document's update level.

The revision history of this document is summarized in the table below.

Table 1. Revision History PN 2002938-001		
B	November 15, 2000	Release B of this manual.

Manual Purpose

This manual contains the instructions necessary to operate the CardioLab II Plus Amplifier safely in accordance with its function and intended use. These instructions include but are not limited to:

- a fundamental description of controls and indicators,
- operating procedures, and
- connection and disconnection of detachable parts and accessories.

Where necessary the manual identifies additional sources of relevant information and/or technical assistance.

Intended Audience

This manual is intended for the person who uses, maintains, and/or troubleshoots this equipment.

Intended Use

The CardioLab II Plus Amplifier is intended for use in an electrophysiological catheter laboratory or catheterization laboratory where ECG, direct cardiac, intracardiac and pressure signals need to be recorded from a patient.

This device is intended for use under the direct supervision of a licensed health care practitioner.

Chapter Content

This manual is organized into the following chapters:

1 Introduction

Describes the manual contents and provides general information about safety precautions, service requirements, equipment symbols and serial number identification.

2 Equipment Overview

Gives a description of the equipment and components.

3 Operation

Describes how to connect and disconnect cables to the amplifier and provides a list of related user's manuals and update guides. Describes the stimulator bypass connections for emergency pacing.

Appendix A: Maintenance and Troubleshooting

Describes how to maintain the equipment and keep it in good working order with a recommended maintenance schedule, cleaning guidelines, checkout procedure, and safety tests.

Appendix B: Technical Information

Provides a complete table of technical specifications for the CardioLab II Plus Amplifier.

Safety Information

Please read all of these instructions carefully. Follow all of the instructions and warnings marked on this product or included in this manual. Save these instructions for later use.

Manufacturer Responsibility

GE Marquette Medical Systems is responsible for the effects of safety, reliability, and performance only if:

- Installation operations, extensions, readjustments, modifications, or repairs are carried out by persons authorized by GE Marquette.
- The equipment is used in accordance with the instructions for use.
- The user attaches only accessory equipment recommended for interaction with the amplifier.

General

The CardioLab II Plus Amplifier maintains leakage currents below medical limits with an isolation transformer, which is incorporated into the design of the amplifier. Amplifier power should be supplied by a dedicated power supply on an isolated circuit for proper behavior of the amplifier.

To ensure patient safety, use only parts and accessories manufactured or recommended by GE Marquette Medical Systems.

This equipment should only be connected as specified by GE Marquette Medical systems. Installation of the equipment should only be performed by qualified GE Marquette Medical Systems service representatives.

Contact GE Marquette Medical Systems before connecting any device to equipment that is not recommended in this manual. Only cables and accessory equipment purchased from GE Marquette Medical Systems should be used in conjunction with the amplifier.

It is important that all of the instructions in this manual be followed, however, these instructions in no way supersede current medical practices regarding patient care and safety.

Parts and accessories used must meet the requirements of the applicable IEC 601 series safety standards, and/or the system configuration must meet the requirements of the IEC 601-1-1 medical electrical systems standard.

Refer servicing of amplifiers under warranty to GE Marquette Medical Systems authorized service personnel. Any attempt to repair equipment under warranty will void that warranty. It is the responsibility of users of systems needing service to contact GE Marquette Medical Systems for servicing of the equipment.

Failure on the part of responsible individuals or institutions to implement a satisfactory equipment maintenance schedule may lead to undue equipment failure and possible health hazards.

The use of ACCESSORY equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:

- use of the accessory in the PATIENT VICINITY; and
- evidence that the safety certification of the ACCESSORY has been performed in accordance to the appropriate IEC 601-1 and/or IEC 601-1-1 harmonized national standard.

The CardioLab II Plus Amplifier is a component/accessory of a Class II medical device.

Equipment Symbols

The following symbols appear on the equipment.

Attention

Pay attention to the documents delivered with the equipment.

Type CF Equipment

Type CF equipment is specifically designed for applications where a conductive connection to the heart is directly established.

Type CF Equipment

Type CF equipment that is defibrillator proof.

Isolated (floating) applied part suitable for intentional external and internal application to the patient including direct cardiac application. "Paddles" outside the box indicate the applied part is defibrillator proof.

[Medical Standard Definition:] F-type applied part (floating/isolated) complying with the specified requirements of IEC 60601-1/UL 2601-1/CSA 601.1. Medical Standards to provide a higher degree of protection against electric shock than that provided by BF applied parts.

Equipotentiality

A nonessential electrical connection which may be used to connect the chassis to other equipment to achieve the same potential.

PD 1000-001, -002, -003, -004, -005

Classifications

The CardioLab II Plus Amplifier is classified, according to IEC-60601-1, as:

Type of protection against electrical shock	**I**
Degree of protection against electrical shock	**CF—ECG, BP, CIM, Auxiliary Inputs**
Degree of protection against harmful ingress of water	**Ordinary**
Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	**Not suitable**
Method(s) of sterilization or disinfection recommended by the manufacturer	**Not Applicable**
Mode of operation	**Continuous operation**

I: Class I equipment

CF: Type CF applied part

Ordinary: Ordinary equipment (enclosed equipment without protection against ingress of water)

Not Suitable: Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide

Underwriters Laboratories Inc. (UL)

Underwriters Laboratories, Inc.

Classified by Underwriters Laboratories Inc. with respect to electric shock, fire, mechanical and other specified hazards, only in accordance with UL 2601-1, CAN/CSA C22.2 No. 601.1, IEC 60601-1, and, if required, IEC 60601-2-27, IEC 60601-2-30, IEC 60601-2-34, IEC 60601-1-1.

Conventions

These are the conventions used in this manual.

Safety Messages

DANGER safety messages indicate an imminently hazardous situation which, if not avoided, WILL result in death or serious injury.

WARNING safety messages indicate a potentially hazardous situation which, if not avoided, COULD result in death or serious injury.

CAUTION safety messages indicate a potentially hazardous situation which, if not avoided may result in minor or moderate injury.

NOTE messages provide additional user information.

Danger, Warnings, and Cautions

DANGER
EXPLOSION HAZARD

Do not use in the presence of flammable anesthetics or other flammable gases.

WARNINGS
ACCESSORIES

Only connect to UL 544 or UL 2601-1 listed or IEC certified medical equipment.

Use only Catheter Input Module (CIM) #301-00202-08 or #301-00203-08 with the CardioLab II Plus Amplifier.

All equipment not complying with IEC 601-1 should be placed outside the patient environment.

ACCIDENTAL SPILLS

If fluid of any kind should leak into the CardioLab II Plus Amplifier, discontinue using the amplifier and contact GE Marquette Medical Systems.

DO NOT allow hydraulic fluid from any device to contact any conductive surface. Hydraulic fluid is electrically conductive.

Do not allow any foreign materials such as fluids to come in contact with the CardioLab II Plus Amplifier.

BACKUP MONITORS

Back-up patient monitors should always be available while using CardioLab II Plus Amplifiers.

CONDUCTIVE CONNECTIONS

Proper connections to the patient are critical for the proper operation of the CardioLab II Plus Amplifier and patient safety. Use extreme caution when making patient connections.

Do NOT connect non-isolated equipment to the amplifier.

Proper connections to the stimulator are critical for the proper operation of the CardioLab II Plus Amplifier and patient safety. Use extreme caution when making stimulator connections. The stimulator must be a IEC 601-1 certified product.

Ablation operations should NOT be executed when a stimulator unit is connected.

Keep the conductive parts of lead electrodes and associated parts away from other conducting parts, including earth ground.

DEFIBRILLATOR PRECAUTIONS

Standby defibrillation equipment is required in the event that the patient needs to be cardioverted or defibrillated.

Do NOT come in contact with the unit or patient during defibrillation.

LEAKAGE CURRENT TEST

When more than two electrical devices are interconnected, the summation of leakage currents must be checked before use and rechecked yearly.

Keep leakage current within acceptable limits when connecting auxiliary equipment to this device.

Total system earth leakage current must not exceed 50 microamperes.

MAINTENANCE

Check the electrical integrity of the signal connections in the catheter input modules and cabling yearly.

Replace only with the same type and rating of fuse.

POWER SUPPLY

To reduce the risk of electric shock or damage to your equipment, do not disable the power cord grounding feature. This equipment is designed for connection to a grounded (earthed) power outlet. The grounding plug is an important safety feature.

Electrostatic discharge (ESD) can damage electronic components. Be sure you are properly grounded when using the CardioLab II Plus Amplifier.

Connect only to a properly earth grounded outlet.

SUPERVISED USE

This device is intended for use under the direct supervision of a licensed health care practitioner.

CAUTIONS

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

ACCURACY

Erroneous values may occur if unused catheter inputs are not properly connected.

DO NOT display any channels which are based on unused catheter input modules. Otherwise erroneous values may occur.

CABLES

Route optical cables though a conduit in the ceiling or floor to avoid damage to the cables or cable connectors.

DEFIBRILLATOR PRECAUTIONS

ECG inputs are protected against the use of a defibrillator in conjunction with the use of the ECG cable.

The pressure inputs on the CardioLab II Plus Amplifier are protected against the use of a defibrillator in conjunction with the use of the recommended pressure trandsucer and reusable cable.

MAINTENANCE

Remove air that is trapped in the transducer or associated tubing by flushing the system according to cath lab procedures.

To reduce the risk of electric shock, DO NOT remove cover (or back). Refer servicing to qualified personnel.

This equipment contains no user serviceable parts. Refer servicing to qualified service personnel.

POWER SUPPLY

The CardioLab II Plus Amplifier may be safely powered by line voltages of 100-240 VAC with frequencies of 50-60 Hz.

Service Information

Service Requirements

Follow the service requirements listed below:

- Refer equipment servicing to GE Marquette Medical Systems authorized service personnel only.
- Any unauthorized attempt to repair equipment under warranty voids that warranty.
- It is the user's responsibility to report the need for service to GE Marquette Medical Systems or to one of their authorized agents.
- Failure on the part of the responsible individual, hospital, or institution using this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.
- Regular maintenance, irrespective of usage, is essential to ensure that the CardioLab II Plus Amplifier will always be functional when required

Equipment Identification

Every GE Marquette Medical Systems device has a unique serial number for identification. The serial number appears on the back of the CardioLab II Plus Amplifier.

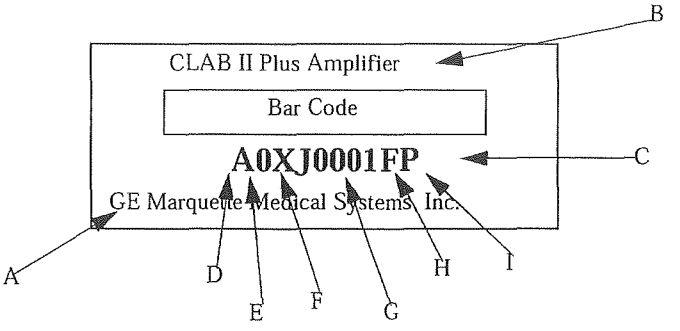

Table 1. Equipment Identifications

Item	Name	Description
A	manufacturer	GE Marquette Medical Systems, Inc.
B	name of device	CLAB II Plus Amplifier
C	serial number	Unique identifier
D	month manufactured	A = January, B = February, C = March, D = April, E = May, F = June, G = July, H = August, J = September, K = October, L = November, M = December
E	year manufactured	9 = 1999, 0= 2000, 1= 2001, (and so on)
F	product code	Two-character product descriptor XJ= CLAB II Plus Amplifier
G	product sequence number	Four-character manufacturing number (of total units manufactured)
H	plant designator	F = Cardiology G = Monitoring
I	device characteristics	One or two characters that further describe the unit, for example: P = prototype not conforming to marketing specification; R = refurbished equipment; S = special product documented under Specials part numbers; U = upgraded unit

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10 Lead ECG Cable 2-10
Power Cord 2-10

For your notes

General Description

The CardioLab II Plus Amplifier is designed to amplify various types of cardiac signals that are acquired from a patient and transmit them back to the Prucka CardioLab/Mac-Lab system, referred to in this manual as the acquisition computer. These signals include 12 Lead ECG, intra-cardiac and pressure signals.

The CardioLab II Plus Amplifier is fully supported by CardioLab EP software versions 3.1 and above and CardioLab Cath software versions 1.0 and above. However, the CardioLab II Plus Amplifier was designed specifically for use with the Prucka CardioLab/Mac-Lab system. The following table lists the functionality of the CardioLab II Plus Amplifier with the different software versions.

Table 1. CardioLab II Plus Functionality for Different Versions of CardioLab Software

CardioLab II Plus Functionality	CardioLab EP 3.1 and Above/CardioLab Cath 1.0 and Above	Prucka CardioLab/Mac-Lab System
Intracardiac	Blocks A and B Only	All Blocks Available
Stimulator	CardioLab II Amplifier Equivalent	Enhanced Switching Options
Auxiliary Input	Not Available	RF Filtered and Unipolar Inputs

The CardioLab II Plus Amplifier supports 32, 64, 96 and 128 channel configurations.

The following list illustrates the number of Catheter Input Modules (CIM) used with the four configurations of the CardioLab II Plus Amplifier:

- 32 Channels: 1 CIM
- 64 Channels: 3 CIMs
- 96 Channels: 5 CIMs
- 128 Channels: 7 CIMs

The Catheter Input Modules for the four configurations of the CardioLab II Plus Amplifier connect to the following catheter inputs on the front of the amplifier:

- 32 Channels: Input A
- 64 Channels: Inputs A-C
- 96 Channels: Inputs A-E
- 128 Channels: Inputs A-G

CardioLab II Plus Amplifier Hardware

Amplifier Part Numbers

The GE Marquette part numbers for the CardioLab II Plus Amplifier are as follows:

- 32 Channel: 2003232-001
- 64 Channel: 2003232-002
- 96 Channel: 2003232-003
- 128 Channel: 2003232-004

If international users need to order a power cord, the following part numbers can be ordered separately.

Table 2. International Power Cord Part Numbers

Part Number	Description
422845-001	Power cord for Continental Europe 10 Amp.
422845-002	Power cord for Britain 10 Amp.
422845-003	Power cord for Italy 10 Amp.
422845-004	Power cord for Swiss 10 Amp.
422845-005	Power cord for India 10 Amp.
422845-006	Power cord for Australia 10 Amp.

Accessory Parts List

GE Marquette recommends the following accessory parts be used with the CardioLab II Plus Amplifier:

Table 3. Accessory Parts List

Accessory Name	Part Number
Abbott Transpac IV Disposable Transducer with 4 ft. extension Cable*	Abbott #42582-08
Abbott Transpac Reusable Cable*	Abbott #42661-04-42
3M Disposable Electrode for ECG Monitoring*	3M Red Dot #2256
* This accessory is not stocked by GE Marquette Medical Systems, Inc.	

Front View

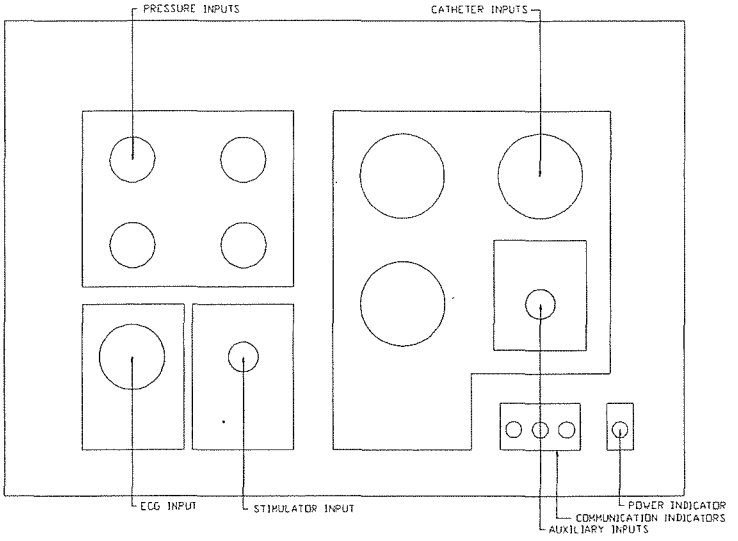


Table 4. Front View 64/32 Channels- CardioLab II Plus Amplifier	
Name	**Description**
Pressure Inputs	Four pressure inputs will each accept a pressure transducer that is calibrated to 5uV/V/mmHg. See the *Accessory Parts List* for GE Marquette recommended pressure transducers.
ECG Input	The ECG input connector will accept a 10 lead ECG input cable.
Stimulator Input	The stimulator input will accept a stimulator input cable. Use the 3 ft., 15 ft. or 30 ft. Touchproof Stimulator Cables (part numbers , 301-00204-03, 301-00204-15, 301-00204-30, respectively) with the CardioLab II Plus Amplifier.
Catheter Inputs	Up to three catheter inputs will each accept a 32 pole catheter input module. Use the CardioLab II Plus Catheter Input Modules (part number 301-00202-08) with the CardioLab II Plus Amplifier.
Auxiliary Inputs	The auxiliary input will accept the Auxiliary Input Cable (part number 301-00205-08).
Power Indicator	The power indicator is on as long as the CardioLab II Plus Amplifier is turned on.
Communication Indicators	Three communication indicators show the status of the communication between the acquisition computer and the CardioLab II Plus Amplifier. ◆ When the XMT indicator is on, the CardioLab II Plus Amplifier is transmitting data to the acquisition computer. The XMT indicator should remain on as long as the power indicator is on. ◆ When the RCV CMD indicator is on, the CardioLab II Plus Amplifier is receiving data from the acquisition computer. The RCV CMD indicator will turn on as long as an instruction is being received by the amplifier. ◆ When the RCV ERR indictor is on, the CardioLab II Plus Amplifier may not be receiving data from the acquisition computer in a valid format or there may be a problem with the fiber optic cable.

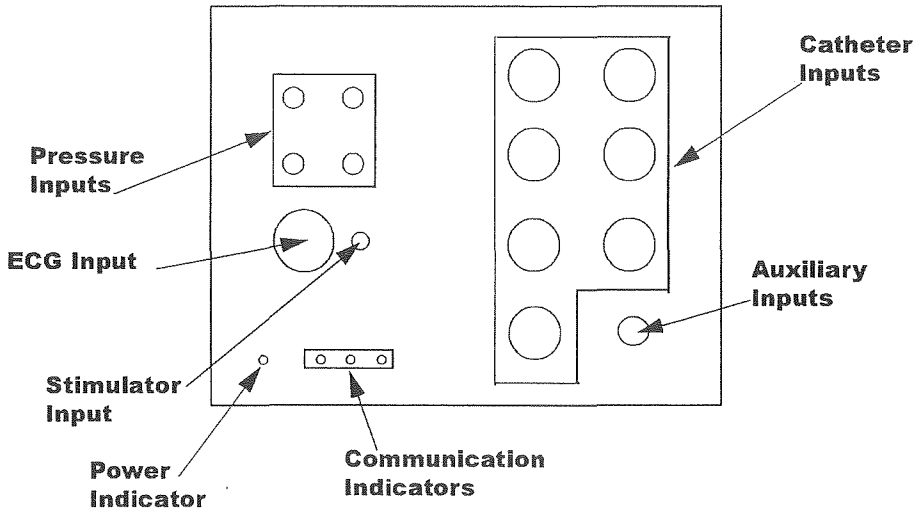


Table 5. Front View 128/96 Channels- CardioLab II Plus Amplifier	
Name	**Description**
Pressure Inputs	Four pressure inputs will each accept a pressure transducer that is calibrated to 5uV/V/mmHg. See the *Accessory Parts List* for GE Marquette recommended pressure transducers.
ECG Input	The ECG input connector will accept a 10 lead ECG input cable.
Stimulator Input	The stimulator input will accept a stimulator input cable. Use the 3 ft., 15 ft. or 30 ft. Touchproof Stimulator Cables (part numbers 301-00204-03, 301-00204-15, 301-00204-30, respectively) with the CardioLab II Plus Amplifier.
Catheter Inputs	Up to seven catheter inputs will each accept a 32 pole catheter input module. Use the CardioLab II Plus Catheter Input Modules (part number 301-00202-08) with the CardioLab II Plus Amplifier.
Auxiliary Inputs	The auxiliary input will accept the Auxiliary Input Cable (part number 301-00205-08).
Power Indicator	The power indicator is on as long as the CardioLab II Plus Amplifier is turned on.
Communication Indicators	Three communication indicators show the status of the communication between the acquisition computer and the CardioLab II Plus Amplifier. ◆ When the XMT indicator is on, the CardioLab II Plus Amplifier is transmitting data to the acquisition computer. The XMT indicator should remain on as long as the power indicator is on. ◆ When the RCV CMD indicator is on, the CardioLab II Plus Amplifier is receiving data from the acquisition computer. The RCV CMD indicator will turn on as long as an instruction is being received by the amplifier. ◆ When the RCV ERR indictor is on, the CardioLab II Plus Amplifier may not be receiving data from the acquisition computer in a valid format or there may be a problem with the fiber optic cable.

Back View

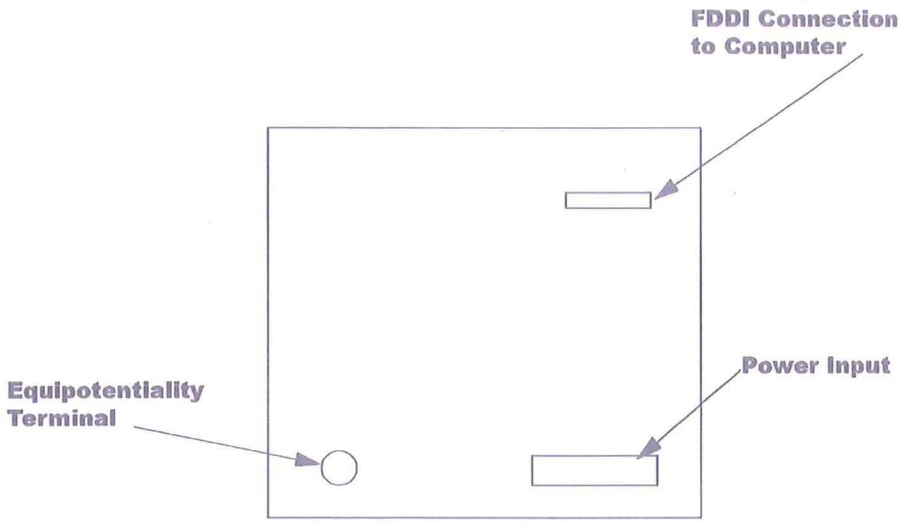


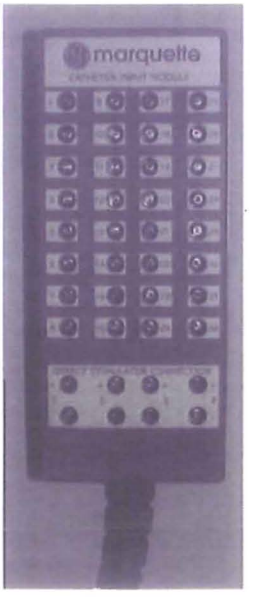
Table 6. Back View - CardioLab II Plus Amplifier	
Name	**Description**
FDDI Connection to Computer	This connector will accept a FDDI type fiber optic cable. The fiber optic cable allows for two-way communication between the amplifier and the CardioLab system.
Power Input	The GE Marquette supplied power cord connects to the Power Input.
Equipotentiality Terminal	The Equipotentiality Terminal is connected to earth ground.

Components

The CardioLab II Plus Amplifier comes with the following components:

Table 7. CardioLab II Plus Amplifier Components	
Component Name	**GE Marquette Part Number**
CardioLab II Plus Catheter Input Module	301-00202-08
3 ft. Touchproof Stimulator Input Cable	301-00204-03
15 ft. Touchproof Stimulator Input Cable	301-00204-15
30 ft. Touchproof Stimulator Input Cable	301-00204-30
Auxiliary Input Cable	301-00205-08
ECG 10 Lead Set	2003421-001
10 Lead ECG Cable	2003419-001
Power Cord	80274-006

CardioLab II Plus Catheter Input Module



PD 1000-016

Catheter Input Modules

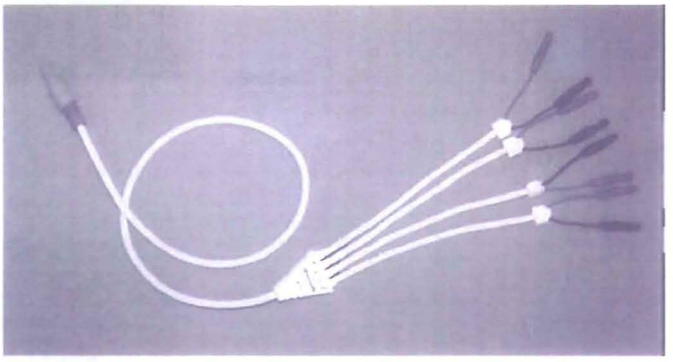
The four stimulus inputs on the Stimulator Input Cable (see photo below) connect to the stimulator.

Each Catheter Input Module is broken down into two groups of 16 poles each. For example, Block A is broken into A (1-16) and A (17-32).

Each pacing channel, requires one positive and one negative pole. In order to maximize the number of pacing channels, only one positive and one negative designation should be made for each group.

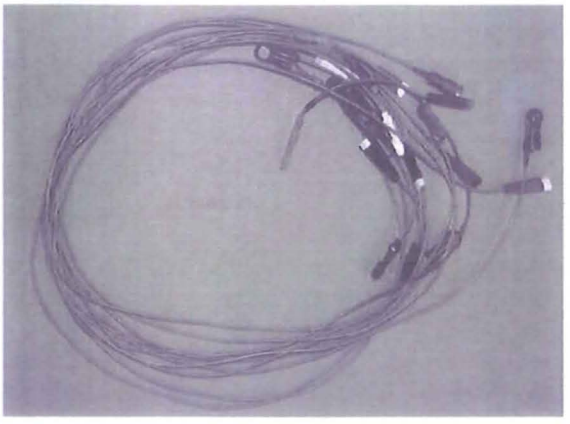
For detailed instructions on how to designate pacing channels and enable pacing for particular sites, refer to the on-line help in the software application.

Stimulator Input Cable



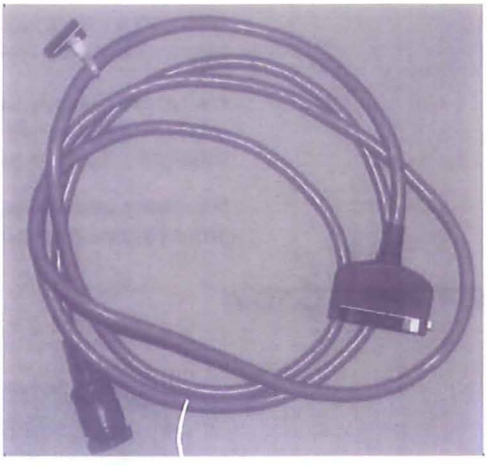
PD 1000-017

ECG 10 Lead Set



PD 1000-018

10 Lead ECG Cable



PD 1000-019

Power Cord

PD 1000-020

3 Operation

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Stimulator Bypass Connections for Emergency Pacing **3-6**

For your notes

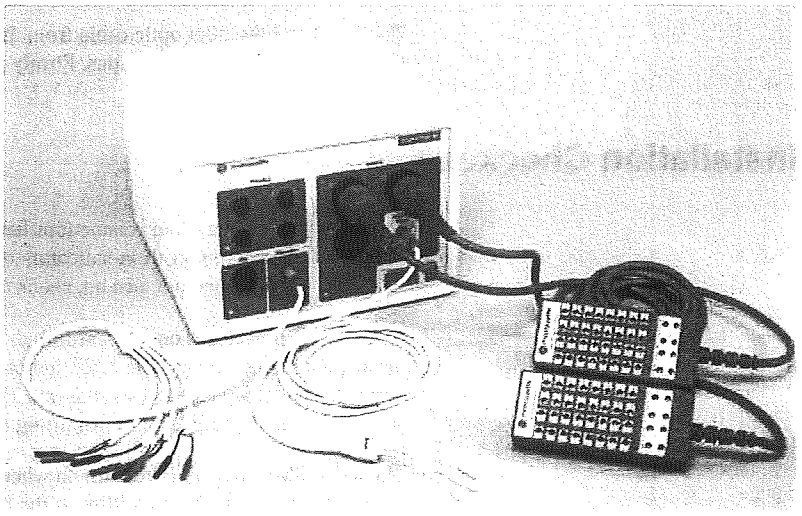
Getting Started

WARNING
Do not allow any foreign materials such as fluids to come in contact with the CardioLab II Plus Amplifier.

If fluid of any kind should leak into the CardioLab II Plus Amplifier, discontinue using the amplifier and contact GE Marquette Medical Systems.

DO NOT allow hydraulic fluid from any device to contact any conductive surface. Hydraulic fluid is electrically conductive.

NOTE: Connect the CardioLab II Plus Amplifier and all accompanying components in a clean and dry environment with a temperature between 0°C and +35°C and a humidity less than 95% relative at 35°C non-condensing.



Connecting Cables to the Amplifier

When making connections to the CardioLab II Plus Amplifier, make sure that the cables are connected securely in the appropriate locations. Refer to *Chapter 2- Equipment Overview* for a description of all equipment and components.

To connect the pressure, ECG, and catheter cables to the amplifier, line the pins with the appropriate connection and firmly push the head of the cable into place. Turn the connector ring to the right (clockwise) to secure the cable into the connection.

To connect the stimulator and auxiliary inputs cables to the amplifier, line the pins with the appropriate connection, hold the head of the cable by the shell and firmly push the cable into place.

To connect the power cord to the back of the amplifier, line the pins with the connection and firmly push the head of the cord into place.

To connect the fiber optic cable to the back of the amplifier, remove the protective cap, hold the cable by the head and firmly push it into place. The cable will only connect in one orientation. **DO NOT** force the fiber optic cable into the connection. If the cable does not connect with ease, flip the cable and try to connect it again.

Disconnecting Cables From the Amplifier

To disconnect the pressure, ECG, and catheter cables from the amplifier, turn the connector ring to the left (counter-clockwise) and firmly pull the cable straight back.

To disconnect the stimulator and auxiliary inputs cables from the amplifier, hold the head of the cable by the shell and firmly pull the cable straight back. The stimulator and auxiliary input cables will not disconnect from the amplifier when pulled by the cord.

To disconnect the power cord from the back of the amplifier, hold the cord by the head and firmly pull the cord straight back.

To disconnect the fiber optic cable from the back of the amplifier, hold the head of the cable while pinching the sides. Firmly pull the cable straight back and attach the protective cap.

Installation Checkout

Once the appropriate cable connections have been made to the CardioLab II Plus Amplifier, the communication indicators on the front of the amplifier should turn on. If the indicators do not turn on, check the fiber optic cable for cracks and wear.

If the XMT indicator is on, the CardioLab II Plus Amplifier is transmitting data to the acquisition computer. The XMT indicator will turn on regardless if the transmission of data is successful or not. The RCV ERR indicator will turn on if the amplifier is having difficulty transmitting data to the computer.

The RCV CMD indicator will turn on when the acquisition computer is sending data to the CardioLab II Plus Amplifier. If the RCV ERR indicator is on, the acquisition computer may be having difficulty transmitting data to the computer.

The RCV ERR indicator may also turn on if the fiber optic cable has been connected to the amplifier incorrectly.

Refer to the manuals listed in the table in the *Related Manuals* section in Chapter 3 for information on configuring and diagnosing the CardioLab II Plus Amplifier using the acquisition computer.

Related Manuals

Refer to the following related manuals for information on configuring channels, stimulus switching, stimulus detection, and enabling and disabling stimulus connections with the CardioLab II Plus Amplifier.

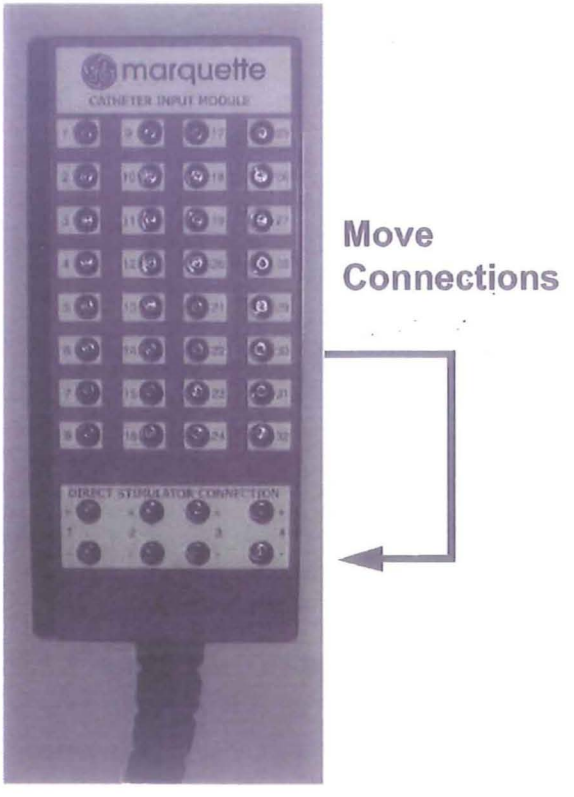
Table 1. Related Manuals	
Manual Name	**GE Marquette Part Number**
CardioLab EP 4.3 Update Guide	003-00304-00
CardioLab EP 4.2 Update Guide	003-00302-00
CardioLab EP 4.1 Update Guide	003-00301-00
CardioLab System EP 4.0 Operator's Manual	003-00200-00
CardioLab EP 3.1 Update Guide	003-00109-00
CardioLab Cath 1.1 User's Guide	003-01202-00
CardioCath 1.0 User's Guide	003-01200-00
Prucka CardioLab/Mac-Lab/ComboLab 2000/4000/7000 Field Service Manual	2002937-003
CardioLab System Field Support Manual	003-00603-02

Stimulator Bypass Connections for Emergency Pacing

The CardioLab II Plus Catheter Input Module features four direct connections to the stimulator that do not rely on the switching capabilities of the amplifier and the acquisition computer. These connections are labeled positive (+) and negative (–) in the Direct Stimulator Connection section of the catheter input module.

In an emergency pacing situation, you can bypass the switching capabilities of the system by simply moving the positive (+) and negative (–) connections from the Catheter Input Module section to the Direct Stimulator Connection section on the CardioLab II Plus Catheter Input Module.

WARNING
Back up patient monitors should always be available while using CardioLab II Plus Amplifiers.



A Appendix A – Maintenance and Troubleshooting

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For your notes

Overview

Maintenance/Repair Log

A "Maintenance/RepairLog" is included in this appendix to aid in keeping a record of the work done on the amplifier.

NOTE: Unless you have an Equipment Maintenance Contract, GE Marquette Medical Systems does not in any manner assume the responsibility for performing the recommended maintenance procedures. The sole responsibility rests with the individual or institution using the equipment. GE Marquette Medical Systems, Inc. service personnel may, at their discretion, follow the procedures provided in this manual as a guide during visits to the equipment site.

Environmental Protection

Even though the amplifier will be operated in many different environments, some precautions must be observed.

- Take care to avoid extremes of temperature, moisture, and humidity. The amplifier is not waterproof.
- Protect the amplifier from spills or other debris. Eating, drinking, and smoking should not be permitted near the amplifier during patient hookup or amplifier maintenance.

Inspection and Cleaning

Since the CardioLab II Plus Amplifier has no moving parts except for the fan, it requires little maintenance. However, to prolong the use of the amplifier, GE Marquette recommends the following maintenance schedule be performed on the amplifier to maintain safe and efficient operation of the unit:

Table 1. Preventative Maintenance Schedule - CardioLab II Plus Amplifier

Maintenance Time	Maintenance Actions
Daily	■ Check the case for cracks or other damage. ■ Inspect all cords and cables for fraying or other damage. ■ Inspect all plugs, cables, and connectors for bent prongs or pins. ■ Verify that all cords and connectors are securely seated. ■ Inspect controls for proper operation.
Weekly	■ Clean the external cables (such as ECG, blood pressure and catheter inputs) and the Catheter Input Module with isopropyl alcohol by wiping the surface with a soft, clean cloth. DO NOT immerse and external cables or the Catheter Input Module in isopropyl alcohol or in fluids of any kind.
Monthly	■ Inspect all tips of the fiber optic cables and, if necessary, clean them with alcohol and a cotton swab. ■ Clean all dust and debris from the fiber optic cable connectors.
Yearly	■ Check the summation of the leakage current. The total system earth leakage current must not exceed 50 microamperes. ■ With the power supply disconnected from the line voltage, check the earth ground connection by verifying that the resistance between the earth terminal of the AC inlet on the amplifier and any exposed metal surface of the enclosure is less than 0.1 ohms. ■ Check the electrical integrity of the signal connections in the catheter input modules. **NOTE:** Yearly maintenance activities on the CardioLab II Plus Amplifier should only be done by qualified technical personnel.

Precautions

Do not open the CardioLab II Plus Amplifier unless instructed to do so by a qualified technical personnel.

Do not immerse any part of the amplifier in water.

Do not use organic solvents, ammonia based solutions, or abrasive cleaning agents which may damage equipment surfaces.

Cleaning

Clean the exterior surfaces with a clean, soft cloth and a mild dishwashing detergent diluted in water.

- Wring the excess water from the cloth. Avoid contact with open vents, plugs, or connectors.
- Do not spray or spill fluid directly on the amplifier.
- Dry the surfaces with a clean cloth or paper towel.

Troubleshooting

If the CardioLab II Plus Amplifier does not transmit and receive signals to and from the CardioLab system, check that:

- The amplifier is plugged in.
- The amplifier power supply is turned on.
- All the cable connections are properly and securely attached.

See the *How to Reach Us* section in Chapter 1 for information on contacting GE Marquette for customer service, product support, supplies, and service parts.

Storing and Transporting the Amplifier

When the amplifier is transported or will not be in use for a long period of time:

- Disconnect and properly store any patient cables.
- Place the amplifier in an environment with a temperature between -15°C to + 50°C and a non-condensing humidity less than 95% relative at 35°C.

Maintenance/Repair Log

Unit Serial Number:

Institution Name:

Date	Maintenance/Repair	Technician

Unit Serial Number:

Institution Name:

Date	Maintenance/Repair	Technician

B Appendix B–Technical Information

Technical Specifications B-3

For your notes

Technical Specifications

Table 1. Technical Specifications - CardioLab II Plus Amplifier	
Item	**Description**
Physical Specifications	
Height	64/32 channel: 9.5 in 128/96 channel: 13.0 in
Width	64/32 channel: 13.0in 128/96 channel: 13.0 in
Depth	64/32 channel: 13.0in 128/96 channel: 13.0 in
Weight	64/32 channel: 25 lbs 128/96 channel: 31 lbs
Environmental Specifications	
Temperature	Operating: 0°C to +30°C non-condensing for Clab II Plus 128 and Clab II Plus 96 Operating: 0°C to +35°C non-condensing for Clab II Plus 64 and Clab II Plus 32
	Transport/Storage: -15°C to + 50°C non-condensing
Humidity	Operating: < 95% relative at 35°C non-condensing
	Transport/Storage: < 95% relative at 35°C non-condensing
Power Specifications:	
Power Requirements	100-240 V AC; 50-60 Hz
Power Input (64/32 channel)	0.0-0.5 Amps Class I, Type CF Continuous operation
Power Input (128/96 channel)	0.5-0.75 Amps Class I, Type CF Continuous operation
Design	
Sampling and Hold	Each channel sampled prior to acquisition.
Sampling Rate	1K, 2K and 4K
Gain Literacy	> 96%
CMMR	100 dB min
Input Impedance	> 1 Million Ohms
Leakage Current	Patient Source: < 10 uA
	Patient Sink: < 10 uA
	Patient Sink (mains voltage on applied part, single fault conditions): < 50 uA

Table 1. Technical Specifications - CardioLab II Plus Amplifier	
	Chassis Leakage: < 100 uA
ECG Input	
Outputs	12 lead ECG produced
High Pass Filter	0.05 Hz, 0.5 Hz, 5 Hz
Low Pass Filter	100 Hz
RF Filtering	All inputs
Gain	50-10,000 in 8 settings
Saturation Recovery	Less than 1 sec.
Notch Filter	Power line (50/60 Hz)
Catheter	
Inputs	32 channel: 32 intracardiac inputs, 4 pressure inputs, 10 ECG inputs 64 channel: 96 intracardiac inputs, 4 pressure inputs, 10 ECG inputs 96 channel: 160 intracardiac inputs, 4 pressure inputs 10 ECG inputs 128 channel: 224 intracardiac inputs, 4 pressure inputs, 10 ECG inputs
Outputs	16 channels/Block. Up to 112 channels. 32 channel: Block A 64 channel: Blocks A-C 96 channel: Blocks A-E 128 channel: Blocks A-G
Switching	Any input can be switched to any output within a Block.
High Pass Filter	DC, 0.05 Hz, 0.5 Hz, 5.0 Hz, 30 Hz, 100 Hz
Low Pass Filter	500 Hz, 2,000 Hz
RF Filtering	All inputs
Gain	50-10,000 in 8 settings
Saturation Recovery	Less than 1 sec.
Notch Filter	Power line (50/60 Hz)
Pressure (4 inputs)	
Inputs	Compatible with all standard external pressure transducers. 5uV/V/mmHg
Input Impedance	> 1 Million Ohms
Outputs	Up to 4 pressure channels
Low Pass Filter	6 Hz, 25 Hz, 100 Hz, 400 Hz
Excitation Voltage	5V DC
Output Impedance	< 0.050 Ohms
Range	-400mm Hg to +400 mmHg
Stimulator (1 input)	

Table 1. Technical Specifications - CardioLab II Plus Amplifier	
Input	4 input channels
Outputs	Each group of 16 poles can only have one active positive (+) stim and one active negative (-) stim.

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